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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,334	03/07/2007	Francesco Santangelo	U 016325-6	9753

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
06/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/583,334	SANTANGELO, FRANCESCO	
	Examiner	Art Unit	
	PHYLLIS SPIVACK	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The finality of the last Office Action is withdrawn.

Claims 3 and 10 remain under consideration.

A Terminal Disclaimer filed March 31, 2011 is acknowledged and has been approved. The rejection of record on the ground of nonstatutory obviousness-type double patenting is withdrawn.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The subject matter under consideration excludes methods of prevention.

Applicant's arguments, filed March 31, 2011, with respect to the rejection of claims 3 and 10 under 35 U.S.C. 103, have been fully considered and are persuasive concerning the administration of N-acetyl cysteine. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of Galli et al., Nephrology, Dialysis, Transplantation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galli et al., Nephrology, Dialysis, Transplantation, in view of Zaloga et al., U.S. Patent 6,060,446, and further in view of Droge et al., U.S. Patent 5,607,974.

In patients undergoing hemodialysis with end-stage renal disease, apoptosis, thiol loss in the peripheral blood mononuclear leukocytes and oxidative stress are significant findings. Galli broadly teaches the administration of exogenous antioxidants to restore a deficit of intracellular thiols. See the Abstract.

Galli does not each the specific administration of cysteine. However, Zaloga teaches the administration of cysteine, as a nutrient, to treat renal failure. See column 4, lines 32-40, where cysteine is characterized as a scavenger of oxygen free radicals, as a substance that reduces renal cellular injury and as a precursor for the antioxidant compound glutathione. Cysteine is also described as cytoprotective in column 5, line 36. Oral administration is disclosed in column 6, line 44. Also see claims 2 and 6, column 8, wherein no effective amount is recited. One skilled in the art, through no more than routine experimentation, would have been able to ascertain an effective amount. Zaloga urges the need for dialysis may be decreased following administration of the nutritional composition of his invention.

Zaloga fails to teach the dosage of cysteine, as required by instant claim 3. However, Droge teaches the oral administration of tablets for countering cysteine deficiency having about 100 mg to 1 gm to patients receiving hemodialysis. See column 2, line 14, as well as column 3, lines 14-19. Droge's teaching encompasses the administration of "any drug" that can be transported into the cytoplasm of the cell and/or elevate plasma thiol levels to provide cysteine (column 2, lines 24-28).

Therefore, one skilled in the renal art would have been motivated to administer cysteine orally to a patient undergoing hemodialysis in order to treat oxidative stress

from the procedure. Such administration would have been obvious because cysteine qualifies as a "thiol supplier," as described by Galli. Cysteine also acts as a scavenger of oxygen free radicals and thus reduces oxidative stress.

No claim is allowed.

Locatelli et al., Nephrology, Dialysis, Transplantation, is cited as state of the art to show the interrelationship of oxidative stress and inflammation in end-stage renal disease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Jeff Lundgren, can be reached on 591-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 15, 2011

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1629